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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	**PAPER NUMBER**
1647	

NOTIFICATION DATE	DELIVERY MODE
02/18/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/569,791	**Applicant(s)** SUWA ET AL.	
	Examiner Marianne P. Allen	**Art Unit** 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 February 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *none*.
   Claim(s) objected to: *none*.
   Claim(s) rejected: *23,26,27,29,31 and 35*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

Continuation of 13. Other: Applicant's amendments do not place the claims in condition for allowance. Claims 9, 23, 26-27, 29, 31, and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in the prior Office actions, there is no basis for the limitation "wherein said candidate substance is a substance that has not yet been determined to be an antidiabetic" in claim 23. Applicant's response does not address this portion of the rejection. Again, claims 40-41 (now cancelled) were not original claims and were considered to constitute new matter. (See amendment adding these claims dated 5/12/08 and new matter rejection for these claims dated 8/21/08.)

As set forth in the prior Office actions, there is no basis for the step of "determining that the candidate antidiabetic substance has a pharmacological action similar to that of said piaglitazone" as recited in claim 23. There is no determination step disclosed or contemplated in the specification at pages 14 or 15.

Applicant points to page 14. This paragraph is reproduced below:

As described above, the present inventors found that the γ -tubulin ring complex is one of molecular targets of the thiazolidine derivative, and that the thiazolidine derivative may improve insulin sensitivity by enhancing the signal of PI3 kinase and/or the action of PPARα via its binding with the γ-tubulin ring complex and exhibit therapeutic effect on insulin resistance.

This is a speculation concerning the activity of the thiazolidine derivative (i.e. pioglitazone) that is not supported by any evidence. It does not speak to the biological activity of the candidate substance being screened in the claimed method. Furthermore, these particular properties are not limitations of the claims. That is, these properties are not evaluated or determined.

Applicant again points to the fourth paragraph on page 15 of the specification for basis. This paragraph is reproduced below:

The candidate substance judged as having interaction with the protein according to the present invention by the screening method of the present invention means that the substance has been screened as a novel antidiabetic having the mechanism of pharmacological action similar to that of the thiazolidine derivative.

The paragraph on page 15 makes an assumption that interaction of the protein with the candidate substance alone leads to the conclusion that the substance a mechanism of pharmacological action similar to that of the thiazolidine derivative. There is reason to doubt the objective truth of this assertion.

The specification discloses that FLJ14797 or SEQ ID NO: 2 binds to pioglitazone, a known antidiabetic substance. See pages 10 and 24-25. The specification discloses that compounds A-1, A-2, and A-3 bind SEQ ID NO: 2. The structures for A-1, A-2, and A-3 are provided on pages 16-17 of the specification. The specification does not disclose that compounds A-1, A-2, and A-3 have the mechanism of pharmacological action similar to a pioglitazone. The specification does not establish that compounds A-1, A-2, and/or A-3 have any antidiabetic properties.

It is again noted that US Patent Publication 2008/0102457 (corresponding to co-pending application 11/718,946) has several inventors in common with the instant application. This application was filed after the instant application. It also discloses FLJ14797. SEQ ID NO: 16 of US Patent Publication 2008/0102457 corresponds to SEQ ID NO: 2 of the instant application. It is interesting to note that this reference does not assert that substances that bind to it are antidiabetic compounds. Rather, FLJ14797 is disclosed as binding ketanserin. Other compounds that bind to FLJ14797 are disclosed as being 5-hydroxytryptamine receptor antagonists or antihypertensive drugs. See at least claims, SEQ ID NO: 16, paragraphs [0054, 0446], and Table 7-2. Thus, applicant's own disclosures demonstrate that screening for the presence or absence of any interaction between the candidate antidiabetic substance and the target protein of SEQ ID NO: 2 alone will not identify an antidiabetic compound. At the time of the invention, applicants themselves did not know what the pharmacological mechanism or properties of SEQ ID NO: 2 were.

It is again noted that pioglitazone was already known and characterized as an antidiabetic. Its interaction with SEQ ID NO: 2 did not identify or characterize these properties. The specification provides no example elucidating the role of SEQ ID NO: 2 in diabetes. There is no evidence of record establishing any role of SEQ ID NO: 2 in diabetes. The specification does not demonstrate that any novel compounds identified as interacting with SEQ ID NO: 2 have any antidiabetic properties. Applicant is again reminded that pioglitazone (for example) has uses in addition to applications in diabetes. Again for example, Hobbs et al. (U.S. Patent No. 7,034,056) discloses uses of pioglitazone in treating obesity. (See at least claim 26.) Again for example, Chandraratna et al. (U.S. Patent No. 7,105,566) discloses uses of pioglitazone in treating vascular trauma. (See at least claim 16.) Thus, the final step of determining that the candidate antidiabetic substance has a pharmacological action similar to that of the thiazolidine derivative is not a determination that the candidate antidiabetic substance has antidiabetic properties. The claims do not require a determination of antidiabetic properties.

In In re Wands (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. In the instant application, there are no working examples, the prior art does not recognize SEQ ID NO: 2 as being involved in diabetes, and the claims are broad. It is not considered to be so predictable that any compound that interacted with SEQ ID NO: 2 would possess antidiabetic properties. The claims are considered to require undue experimentation to practice.

No claims are allowed.